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Cardinal Health, Inc. 1500 Waukegan Road West Building Waukegan, IL 60085			STRANSKY, KATRINA MARIE	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte REINDER N. LAP

Appeal 2013-008917¹
Application 11/480,057²
Technology Center 3700

Before PHILIP J. HOFFMANN, KEVIN W. CHERRY, and
TARA L. HUTCHINGS, *Administrative Patent Judges*.

HUTCHINGS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant appeals under 35 U.S.C. § 134(a) from the Examiner's final rejection of claims 1–14. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ Our decision will refer to Appellant's Appeal Brief ("App. Br.," filed Jan. 10, 2011) and Reply Brief ("Reply Br.," filed July 6, 2011), and the Examiner's Answer ("Ans.," mailed May 5, 2011), Advisory Action ("Adv. Act.," mailed July 28, 2010), and Final Office Action ("Final Act.," mailed May 12, 2010).

² Appellant identifies Cordis Corporation as the real party in interest. App. Br. 2.

CLAIMED INVENTION

Appellant's claimed invention "relates generally to medical devices, and more particularly to a resilient protection sleeve for balloon catheters." Spec. ¶ 2.

Claim 1, reproduced below, is the sole independent claim on appeal and is representative of the subject matter on appeal:

1. A balloon catheter system for medically treating a patient, comprising:

a balloon catheter having a catheter shaft extending from a proximal end to a distal end, a balloon affixed to the catheter shaft at or near its distal end, and a hub affixed to the catheter shaft at or near its proximal end;

wherein the shaft defines a longitudinal axis, an inflation lumen and a guidewire lumen, the guidewire lumen extending between a proximal guidewire port and a distal guidewire port, the inflation lumen extending between a proximal port defined by the hub and an interior of the balloon;

wherein the balloon has a central inflatable portion between a proximal collar and a distal collar, the collars each being affixed to the catheter shaft; the balloon in an initial configuration being deflated, pleated and wrapped around the catheter shaft; and

a resilient protective sleeve around the balloon, the sleeve having at least one tubular portion and at least one wing extending outward, each wing defining a channel and resiliently clamping the sleeve around the balloon, each tubular portion extending circumferentially between each wing, the sleeve having a longitudinal length corresponding to a longitudinal length of the balloon, such that the sleeve protects and compresses the balloon.

REJECTIONS

The following rejections are before us for review:

Claims 1–7 and 9–13 are rejected under 35 U.S.C. § 102(b) as anticipated by Bigus (US 6,629,992 B2, iss. Oct. 7, 2003).

Claims 1–7 and 9–14 are rejected under 35 U.S.C. § 103(a) as unpatentable over Armstrong (US 6,899,727 B2, iss. May 31, 2005) and Bigus.

Claim 8 is rejected under 35 U.S.C. § 103(a) as unpatentable over Armstrong, Bigus, and Holman (US 2006/0074476 A1, pub. Apr. 6, 2006).

ANALYSIS

Anticipation

Independent Claim 1 and Dependent Claims 2–7 and 9–13

We are persuaded by Appellant’s argument that Bigus does not disclose a “a resilient protective sleeve . . . having . . . at least one wing extending outward, each wing defining a channel and resiliently clamping the sleeve around the balloon,” as recited in claim 1. App. Br. 4–5; *see also* Reply Br. 2–3. The Examiner relies on Bigus at Figure 6 as disclosing the argued limitation. Final Act. 2–3; *see also* Ans. 8.

Bigus relates to biocompatible or bioabsorbable sheaths for self-expanding stents. Figure 6 of Bigus shows sheath 16 having thinned portions 54. Bigus, col. 7, ll. 5–8. When sheath 16 is expanded, it fails at thinner portions 54. By selectively positioning thinned portions 54, Bigus’s sheath assists in controlled stent deployment. *Id.* at col. 7, ll. 9–14.

The Examiner interprets Bigus's thinned portions 54 as channels, and the two thicker portions adjacent a thinned portion as wings. Ans. 8. In this regard, the Examiner finds that "each wing [of Bigus's sheath 16] defin[es] a *portion of the channel that lies between them.*" Adv. Act. 2 (emphasis added).

During prosecution, the PTO gives claims their "broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000) (citation omitted). Under this broadest reasonable interpretation standard, claim terms are given their ordinary and customary meaning as it would be understood by a person of ordinary skill in the art in light of the specification. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

Here, the Specification describes with reference to Figures 1 and 2 that a U-shaped wing 14 defines a channel 16 within the U-shape of the wing. *See Spec.*, Figs. 1, 2, ¶ 25. In our view, one of ordinary skill in the art would understand from the Specification that the phrase "each wing defines a channel," as recited in claim 1, requires each wing to define a channel, not a portion of the channel as the Examiner proposes. We agree with Appellant that each of Bigus's thickened portions does not define a channel, as called for in claim 1.

Therefore, we reverse the Examiner's rejection of claim 1 under 35 U.S.C. § 102(b). We also reverse the Examiner's rejection of claims 2–7 and 9–13 under 35 U.S.C. § 102(b), which depend from claim 1.

Obviousness

Independent Claim 1 and Dependent Claims 2–7 and 9–14

We are persuaded by Appellant’s argument that Armstrong does not disclose a “a resilient protective sleeve . . . having . . . at least one wing extending outward, each wing defining a channel and resiliently clamping the sleeve around the balloon,” as recited in claim 1. App. Br. 7–5. The Examiner relies on Armstrong at Figures 14B–14G as disclosing a resilient protective sleeve 11 having at least one wing 140 extending outward, each wing defining a channel and resiliently clamping the sleeve around the balloon. Final Act. 3–4; *see also* Ans. 9.

Armstrong relates to transcatheter delivery and remote deployment of implantable medical devices of the self-expanding or balloon expandable type. Armstrong, col. 1, ll. 6–9. As shown in Figure 14B of Armstrong, constraining sheath 11 is fitted around a compacted endoprosthesis 12 and a catheter balloon 15 (i.e., the stent and balloon are at their compacted diameter for insertion into the vasculature). *Id.* at col. 10, l. 63–col. 11, l. 1. Excess material of constraining sheath 11 results in flap 140. *Id.* at col. 11, ll. 1–2. Flap 140 is thermally bonded together at opposing inner surfaces 142. *Id.* at col. 11, ll. 7–9. Inflation of catheter balloon 15 easily separates the bonds, allowing endoprosthesis 12 to deploy to its full diameter. *Id.* at col. 11, ll. 9–12, 19–25.

The Examiner takes the position that the excess sheath material 140 resiliently clamps the sleeve around the balloon. However, Armstrong’s flap 140 is designed to easily separate when the balloon is inflated and, thus, does not resiliently clamp the sleeve around the balloon, as required by claim 1.

Therefore, we reverse the Examiner's rejection of claim 1 under 35 U.S.C. § 103(a). We also reverse the Examiner's rejection of claims 2–7 and 9–14 under 35 U.S.C. § 102(b), which depend from claim 1.

Dependent Claim 8

Claim 8 depends from claim 1. The Examiner's rejection of claim 8 based on Holman, in combination with Armstrong and Bigus, does not cure the deficiency in the Examiner's rejection of claim 1. Therefore, we do not sustain the Examiner's rejection of claim 8 under 35 U.S.C. § 103(a) for the same reasons set forth above with respect to claim 1.

DECISION

The Examiner's rejection of claims 1–7 and 9–13 under 35 U.S.C. § 102(b) is reversed.

The Examiner's rejections of claims 1–14 under 35 U.S.C. § 103(a) are reversed.

REVERSED